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466	7590	01/22/2008	EXAMINER	
YOUNG & THOMPSON			KOSLOW, CAROL M	
745 SOUTH 23RD STREET				
2ND FLOOR			ART UNIT	PAPER NUMBER
ARLINGTON, VA 22202			1793	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,084

Applicant(s)

ENGQVIST ET AL.

Examiner

C. Melissa Koslow

Art Unit

1793

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 28-60 is/are pending in the application.
- 4a) Of the above claim(s) 28-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 39-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Applicant's election with traverse of Group I in the reply filed on 13 November 2007 is acknowledged. The traversal is on the grounds that it is not a serious burden to search all the groups and the fact a lack of unity holding was not made by the International Searching Authority. This is not found persuasive because the serious burden is not a factor in determining if a lack of unity restriction is appropriate and the fact that a lack of unity holding was not made by the International Searching Authority is immaterial as to whether a lack of unity holding is appropriate or not.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement.

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered.

Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "1" in figures 1-4 and "3" in figure 5 have both been used to designate an implant with a metal, ceramic or polymeric substrate. In addition, figures 2 and 3 use "3" to designate an outer layer composed of non-reacted CA that comprises phosphate (pg. 11, lines 14-15). Thus "3" has been used to designate both an outer layer composed of non-reacted CA that comprises phosphate and an implant with a metal, ceramic or polymeric substrate. The drawings are objected to because the figure on page 2/2 is not labeled as figure 6 and it includes Swedish language labels.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of

an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The disclosure is objected to because of the following informalities:

Applicants use the term "phosphor" to mean "phosphorous" throughout the specification. This use is improper since "phosphor" is not a synonym for phosphorous. The term "phosphor" refers to phosphorescent materials and thus applicants' use of this term to mean "phosphorous" is improper. The specification teaches "a phase that has a capacity to form water soluble phosphate". It is unclear what is meant by this phrase and it is unclear what phases or compounds are encompassed by this phrase. There are no examples of compounds which are encompassed by this phrase. The specification only discloses water soluble phosphate compounds. Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The subject matter of claims 3 and 4 are not found in the specification. The specification teaches the maximum volume% of apatite formed during hydration is 30 vol% and that the liquid has a pH of at least 7. The specification is silent as to the pH of the system. The teaching in claims 50 and 58 that the salt can be citrates is not found in the specification. Finally, the teaching of claim 56 that the phosphate ion can be hydro-ammonium phosphate is not found in the specification. It is noted that the subject discussed above is all found in the originally filed claims and thus re part of the originally filed disclosure.

Claim 60 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

This claim state the system is for an implant material when hydrated to provide a coating layer having a thickness of 0.5-20 microns. It is unclear how this claim further defines or limits the system of claim 1. The intended use of the system does not appear to impart any compositional limit on the system and there is no indication in the specification that the intended use of the system imparts any compositional limit on the system.

Claims 5, 45, 49, 51, 52, 54 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 45 is new matter since the claimed subject matter is not found in the original disclosure. There is no teaching in the originally filed disclosure that the powder material has a crystal size of at most 5 microns. The originally filed disclosure teaches the crystal size in the hydrated composition and non-reacted CA that comprises phosphate is 5 microns or less (page 11) or that the binder phase of C_3A , C_2S and/or C_3S has a particle size of less than 5 microns. These teachings do not support new claim 45.

Claim 5 teaches a C_3A , C_2S and/or C_3S has a particle size of at most 5 microns, but page 4 teaches C_3A , C_2S and/or C_3S has a particle size of less than 5 microns. This different in particle

size needs to be clarified. Page 5 teaches the amount of a non-difficultly soluble fluoride containing phase is below 10%, but claim 49 teaches the amount is 0.5-10%. This difference in amount needs to be clarified. Page 6 teaches that the phosphorous can be supplied to the system from phosphate or phosphorous coated particles. Claim 51 teaches the phosphate or phosphate-forming phase exists as particles coated with phosphate or phosphate-containing phase. Page 6 also teaches solid solutions of phosphorous and a cement phase. Claim 52 teaches a solid solution of the cement phase and a phosphate containing phase. These differences in the composition between what is claimed and that in the specification need to be clarified. Page 8 teaches the concentration of phosphate ions in the hydration liquid is 0.01-5 M. Claims 54 and 55 teach the amount of water soluble phosphate or a phase that has a capacity to form water soluble phosphate is present in an amount of 0.01-5 M. Phosphate ions are different from water soluble phosphate or a phase that has a capacity to form water soluble phosphate. This difference in composition needs to be clarified.

Claims 1-4 and 39-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 39-60 are indefinite since it is unclear what is meant by "a phase that has a capacity to form water soluble phosphate" and it is unclear what phases or compounds are encompassed by this phrase. There are no examples of compounds which are encompassed by this phrase. The specification only discloses water soluble phosphate compounds. Claim 47 is indefinite since it is unclear if these grains are composed of the water soluble phosphate, phase that has a capacity to form water soluble phosphate or a different phosphate composition. Claims

54 and 55 are duplicates since there is no indication in the specification that the intended use of the system affects the composition of hydration liquid. Claim 56 is indefinite since hydro-ammonium phosphate is not a phosphate ion. It is a phosphate salt. Finally, Claim 60 is indefinite since it is unclear what is being claimed. As discussed above, the use of the system as an implant material does not impart any composition limitation on the system and the thickness of a result coating layer does not further limit or define the system.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 39-41, 43, 45-50, 53-56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Re. 33,221.

This reference teaches a calcium phosphate dental cement that forms hydroxyapatite upon hydration comprising a powder composition having a particle size of 5 microns or less and comprising least two sparingly soluble calcium phosphates and an aqueous hydration liquid. The examples teach a system of a powder containing a mixture of calcium phosphates and an aqueous phosphoric acid solution, where the amount of phosphoric acid is 0.02 M. The reference does not teach the volume percentages of hydroxyapatite formed, but since the taught system is identical to that claimed, it must produce a volume percent that falls within the claimed ranges, absent any showing to the contrary. The taught system and/or hydration liquid has a pH of 7 or above. Since the calcium phosphate cements are free of aluminum, they have a molar content of calcium than aluminum. The reference teaches the liquid or powder can contain phosphoric acid

or sodium phosphates. It teaches the powder can contain hydroxyapatite particles, or grains; and high-molecular proteins. The reference teaches liquid or powder can contain about 3.8 wt% of a non-difficultly soluble fluoride compound; soluble calcium, magnesium and strontium compounds which have the capacity to form the claimed salts, citrates and carbonates. The reference teaches the claimed system.

Claims 1-3, 39-41, 44, 46-47, 49 and 53-56 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent 4,959,104.

This reference teaches a calcium phosphate based cement system of a powder containing calcium phosphates and an aqueous liquid, where the cement forms fluoroapatite upon hydration. The reference teaches a system of a powder mixture of calcium phosphates, an inorganic fluoride, such as calcium fluoride, and phosphoric acid or alkali metal salts thereof and the liquid is water; a system of powder mixture of calcium phosphates and an inorganic fluoride, such as calcium fluoride and an aqueous acid solution, where the acid is phosphoric acid or alkali metal salts thereof and a system of powder mixture of calcium phosphates and an aqueous solution of an acid and a water soluble fluoride, where the acid is phosphoric acid or alkali metal salts thereof. The reference does not teach the volume percentages of hydroxyapatite formed, but since the taught system is identical to that claimed, it must produce a volume percent that falls within the claimed ranges, absent any showing to the contrary. Since the calcium phosphate cements are free of aluminum, they have a molar content of calcium than aluminum. The reference teaches the fluoride acts as an accelerator. The examples teach the amount of the inorganic fluoride is 2.5-6.6 %, which falls within the claimed range. The reference teaches the

amount of phosphate ions in the solution is 0.02-3 M, which falls within the claimed range. The reference teaches the claimed system.

Claims 1-4, 39-41, 53-56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent 5,342,441.

This reference teaches a calcium phosphate based cement system of a powder containing calcium phosphates and an aqueous liquid, where the cement forms hydroxyapatite upon hydration. The powder component contains calcium phosphates and the liquid component contains 0.02-0.5 M phosphate ions from an alkali phosphate and 0.001-2 M of an organic ion, such as citrate. The system has a weakly basic pH, which means it has a pH greater than 7. The reference does not teach the volume percentages of hydroxyapatite formed, but since the taught system is identical to that claimed, it must produce a volume percent that falls within the claimed ranges, absent any showing to the contrary. Since the calcium phosphate cements are free of aluminum, they have a molar content of calcium than aluminum. The reference teaches the claimed system.

Claims 1-4, 39-41, 43, 45, 53-56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent 5,525,148.

This reference teaches a calcium phosphate based cement system of a powder containing calcium phosphates and an aqueous liquid containing 0.5-5 M of a sodium phosphate, where the cement forms hydroxyapatite upon hydration. The system and aqueous liquid have a pH above 7. The reference does not teach the volume percentages of hydroxyapatite formed, but since the taught system is identical to that claimed, it must produce a volume percent that falls within the claimed ranges, absent any showing to the contrary. Since the calcium phosphate cements are

free of aluminum, they have a molar content of calcium than aluminum. The example uses powders which have a particle size of less than 5 microns. The examples teach the solution contains sodium ions which are biologically existing ions that can form oxalate, lactate and citrate salts. The reference teaches the claimed system.

Claims 1-3, 40, 41, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent 6,143,069.

This reference teaches a hydraulic cement system comprising a powder comprising calcium aluminate, sodium polyphosphate and water. This system forms hydroxyapatite during hydration (col. 3, lines 19-22). The reference does not teach the volume percentages of hydroxyapatite formed, but since the taught system is identical to that claimed, it must produce a volume percent that falls within the claimed ranges, absent any showing to the contrary. The reference teaches the claimed system.

Claim 5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

There is no teaching or suggestion in the cited art of a system comprising a powdered material comprising a binder phase consisting essentially of at least one of $3\text{CaO} \cdot \text{Al}_2\text{O}_3$, $3\text{CaO} \cdot \text{SiO}_2$ and $2\text{CaO} \cdot \text{SiO}_2$ having a mean particle size of at most 5 microns and a water based hydration liquid comprising phosphoric acid and tricalcium phosphate where when the liquid and powdered material are mixed apatite is formed during hydration of the binder phase.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Koslow whose telephone number is (571) 272-1371. The examiner can normally be reached on Monday-Friday from 8:00 AM to 3:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo, can be reached at (571) 272-1233.

The fax number for all official communications is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cmk
January 18, 2008


C. Melissa Koslow
Primary Examiner
Art Unit 1793